

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL No. 04-MD-1592 (MLW)

Civil Action No. 04-10470-MLW
C.D. Cal. No. CV 02-4349 MRP (CWx)

**COLUMBIA UNIVERSITY'S BRIEF IN OPPOSITION TO AMGEN'S MOTION TO
AMEND AND SUPPLEMENT COMPLAINT**

Dated: December 22, 2004

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Amgen's motion to amend presupposes how the Court will rule on two significant issues now pending before the Court, both of which logically should be resolved before this Court decides whether Amgen should be permitted to file its proposed fourth pleading in this action. Those two important issues are: first, whether any of Amgen's claims remain after the Court's ruling on Columbia's motion to dismiss, and, second, whether the Court should grant Columbia's pending request to remand any surviving claims in the Amgen action—regardless of how they may be characterized—to the court in which Amgen originally chose to file this action.

Before the Court rules on Amgen's motion to amend, it should first determine whether any of Amgen's declaratory judgment claims continue to exist and thus may be amended. Columbia and Amgen have presented sharply conflicting positions on the scope of the Court's Order granting Columbia's motion to dismiss, and this Court has yet to rule on that dispute. As set forth in the parties' recent Joint Report, Columbia's position is that the Court's Order dismissed all of Amgen's declaratory judgment claims. *See* Nov. 5, 2004 Order, at p.18 (“[T]here is no risk that [plaintiffs] will be required to pay Columbia damages for their current activities or products even if the ‘275 patent is reissued with new or amended claims. Accordingly, the reasons for the Declaratory Judgment Act no longer pertain to this case. More significantly, no actual cases or controversies any longer exist.”) (internal citations omitted). Amgen, in contrast, contends that its First and Seventh Claims for Relief survived the Court's Order. If the Court agrees with Columbia's position, it should deny Amgen's motion to amend outright because Amgen has no declaratory judgment claims left to amend or supplement.

Even if the Court agrees with Amgen that one or both of the First and Seventh Claims for Relief survive the motion to dismiss, the Court should go on to determine whether it will, as

Columbia has requested, make a suggestion of remand to the Judicial Panel on Multidistrict Litigation ("JPML"). If the Court is inclined to suggest remand, it makes sense to leave the decision on Amgen's motion to amend to the Central District of California, which has previously ruled on two motions to dismiss pertaining to the very same Seventh Claim for Relief now at issue.

If, however, this Court reaches the merits of Amgen's motion to amend, the motion should be denied. Amgen has filed three complaints in this action, all originally in the Central District of California, and now proposes to file its fourth. When the Central District of California permitted the filing of Amgen's Second Amended Complaint, the district judge *specifically ordered that no further amendments shall be permitted*. Nowhere in the pending motion to amend does Amgen disclose this fact to the Court, and nowhere in the pending motion does Amgen explain why it should be allowed to end-run the district court's earlier, unequivocal ruling in this regard.

II. FACTUAL BACKGROUND

The first three patents relevant to this litigation (the "original Axel patents") were issued in 1983, 1987, and 1993, respectively. Each of these original Axel patents expired on August 16, 2000. More than two years later, on September 24, 2002, the Patent Office issued Columbia's '275 patent, with which this Court is familiar.

In 1989, Amgen and Columbia entered into a licensing agreement for the Axel patent portfolio, and shortly thereafter Amgen began paying royalties under that agreement. Unlike all of the other plaintiffs in this MDL proceeding, however, Amgen ceased paying royalties for its licensed products on the day the original Axel patents expired, August 16, 2000. And unlike all of the other plaintiffs, Amgen has never paid any royalties on the estimated two years or more of

licensed product that it manufactured *during the term of the original Axel patents*, and had on hand as of the date the original Axel patents expired, but sold after that date. As a result of this abrupt termination of royalty payments, Amgen breached its contractual obligations to Columbia, and is estimated to owe Columbia well in excess of \$100 million.

III. PROCEDURAL HISTORY

A. Proceedings In The Central District Of California

Amgen's original Complaint, and its later-filed First Amended Complaint, alleged claims pertaining to the '275 patent and the related '159 application (the last Axel patent application pending in the Patent Office, other than the application to reissue the '275 patent). Each of the claims asserted the invalidity, unenforceability, or non-infringement of the '275 patent. The Central District of California dismissed the Seventh Claim for Relief in Amgen's First Amended Complaint, but gave Amgen an opportunity to amend that claim. Amgen filed its Second Amended Complaint in this action on December 10, 2003.

Amgen's Seventh Claim asserts the theory that Columbia had a contractual obligation under the license to refrain from "repressive practices" and that this obligation was a condition to Amgen's obligation to pay royalties on the '275 patent. Amgen alleges that Columbia failed to fulfill this condition, and that Amgen was therefore relieved of its obligation to pay royalties under the license agreement based on the existence of the '275 patent. Although the Central District of California denied Columbia's second effort to dismiss the Seventh Claim for Relief, the district court expressed considerable skepticism of the merits of Amgen's Seventh Claim:

In allowing this claim [Amgen's Seventh Claim for Relief], . . . this Court cautions the Plaintiffs that stating a claim is a far cry from being able to prove one. Although this Court will remain open to further evidence and argument, review thus far suggests that Plaintiffs' Seventh Claim is unlikely to survive a dispositive motion.

See Jan. 29, 2004 Order, at 6, attached as Exh. A.¹ Notably, District Judge Pfaelzer specifically ruled that Amgen would *not* be permitted to make additional amendments to the pleadings:

This Court assumes that the Plaintiffs [Amgen and Immunex] have now asserted all of the claims they intend to assert. *Further leave to amend will not be granted.*

Id. at n.2 (emphasis added).

Columbia then filed its counterclaims against Amgen, seeking to recover the royalties owed by Amgen under the licensing agreement for manufacture of licensed products during the term of the original Axel patents.

B. MDL Proceedings

The JPML ordered the Amgen case consolidated with the other lawsuits brought by licensees to the Axel portfolio who were also challenging the ‘275 patent. In doing so, the JPML specifically noted that the reason for consolidation was that each lawsuit presented common questions relating to the validity and enforceability of the ‘275 patent.

Columbia subsequently filed a covenant not to sue the plaintiffs for infringement of the ‘275 patent, thus divesting this Court of subject matter jurisdiction over plaintiffs' declaratory judgment claims relating to the ‘275 patent. Columbia moved to dismiss all declaratory relief

¹ The district court also stated, “It is not without hesitation that this Court is allowing the Plaintiffs’ Seventh Claim for Relief to remain in this case. The Motion to Dismiss is denied because, utilizing creativity and imagination, there conceivably could be a scenario whereby Plaintiffs could show that their license agreements contained a condition and this condition was unsatisfied . . . At this stage it appears highly unlikely that this scenario will be supported by the facts. It is unlikely that the language the Plaintiffs reference actually creates a condition. Even if it did, this Court’s experience suggests that the ‘repressive practices’ language is a reference to anti-competitive activities, not to the kinds of inequitable conduct and patent misuse claims Plaintiffs’ counsel offered as examples repressive practices [sic]. Nevertheless, although this Court suspects that upon a proper motion on a more developed record the Seventh Claim will be defeated, the Court will allow the Plaintiffs to attempt to make their case.” *See id.* at 11.

claims relating to the '275 patent for lack of subject matter jurisdiction and requested a suggestion of remand for the few remaining claims, including its contract counterclaims against Amgen based on royalty obligations arising under the original Axel patents.

This Court granted Columbia's motion to dismiss on November 5, 2004. It ordered the parties to confer and file a report on their respective positions as to which claims survived the dismissal order. The parties filed their Joint Report on December 6, 2004. The Court has not yet resolved the issues raised by the Joint Report or Columbia's request for suggestion of remand.

IV. DISCUSSION

A. The Court Should First Address Whether Its November 5, 2004 Order Dismissed Amgen's First And Seventh Claims For Relief

The Court has already ruled that, in light of Columbia's covenant not to sue, there is no subject matter jurisdiction over Amgen's claims seeking declaratory judgment regarding the '275 patent. *See* Nov. 5, 2004 Order, at p.18. To avoid the impact of that ruling, Amgen now takes the position that its First and Seventh Claims also pertain to the *original* Axel patents.² No other plaintiff in this litigation is seeking any form of declaratory relief with respect to the original Axel patents, and Amgen itself has never made this assertion before now. Nor should the Court give any credence to Amgen's untimely effort to reformulate its claims.

If Amgen truly believed that its First and Seventh Claims were broad enough to relate to the original Axel patents, it had enormous incentive and abundant opportunity to make that

² At the same time—in an obvious effort to avoid remand—Amgen insists that its allegations about Columbia's conduct with respect to the later-issued '275 patent somehow remain relevant to its claims under the *original* Axel patents. Amgen would apparently have this Court believe that conduct allegedly occurring in 2002 (and later) relating to the '275 patent somehow excuses a royalty obligation that arose no later than August 16, 2000 based on the original Axel patents.

argument *before* the Court addressed Columbia's motion to dismiss, both in its opposition brief and at the hearing on the motion. Amgen nevertheless chose to wait until after the Court granted Columbia's motion to make this argument for the very first time. This Court made clear at the hearing on the motion to dismiss that it would rule on the basis of the record then before the Court. Oct. 6, 2004 Hearing, at 130-131 ("You've had the briefing and the motion to dismiss . . . So I'm going to decide the case on the record as it now stands.").

In opposition to the motion to dismiss, the only claims that Amgen argued should survive were its attorneys' fees claim and its First Claim for Relief as to royalties owed *based on the '159 application and/or '275 patent*. Amgen *never* asserted or even suggested that its First Claim for Relief should also survive because it somehow pertains to the *original* Axel patents. Moreover, Amgen never discussed or even *mentioned* its Seventh Claim for Relief anywhere in its opposition brief or at the hearing.

An examination of the language and history of those claims belies Amgen's belated argument that they relate to the original Axel patents. Amgen's First and Seventh Claims for Relief, as currently plead, pertain solely to Amgen's obligations to pay royalties based on the '275 patent for product manufactured *after* the original Axel patents expired in August of 2000. *See* Joint Report, filed Dec. 6, 2004, at pp.5-7. The Court's Order dismissing Amgen's declaratory relief claims for lack of subject-matter jurisdiction thus extends to the First and Seventh Claims.

If Amgen does not have any claims remaining to amend or supplement, its motion should be denied. Once claims have been dismissed, courts routinely exercise their discretion to deny

leave to amend.³ *See, e.g., In re Merrill Lynch & Co., Inc. Research Reports Sec. Litig.* (MDL No. 1484), 273 F. Supp. 2d 351, 391 (S.D.N.Y. 2003) (denying motion to amend where filed after court granted motion to dismiss; the delay showed "bad faith of [plaintiff] in waiting to see how he would fare on the prior motion to dismiss") (internal citation and quotation omitted); *In re Recombinant DNA Tech. Patent and Contract Litig.* (MDL No. 912), 874 F. Supp. 904, 918 (S.D. Ind. 1994) (denying motion to amend to add facts in support of a claim that the court arguably previously dismissed when facts were already known to plaintiff, yet plaintiff had failed to present them in opposition to motion to dismiss and facts were largely cumulative); *see also Cowen v. Bank United of Texas, FSB*, 70 F.3d 937, 944 (7th Cir. 1995) (denying motion to amend filed during pendency of summary judgment motion, noting that plaintiff "may be maneuvering desperately to stave off the immediate dismissal of the case").

This is especially true when claims have been dismissed for lack of subject-matter jurisdiction, as they were here. *See Pressroom Unions-Printers League Income Sec. Fund v. Continental Assurance Co.*, 700 F.2d 889, 893 (2d Cir. 1983) (denying motion to amend because plaintiff "seeks not to remedy inadequate jurisdictional allegations, but rather to substitute a new action over which there is jurisdiction for one where it did not exist").

³ Thus, Amgen's motion to amend should be denied with respect to its Third Claim, regardless of the Court's conclusion on Amgen's First and Seventh Claims. Amgen admits that the Third Claim did not survive the Court's dismissal order. In any event, amendment of the Third Claim would be futile. Even if Amgen's contention that the original Axel patents are unenforceable succeeded, Amgen's royalty obligations are unaffected. Under binding Federal Circuit law, a licensee is responsible for all royalty obligations that accrued before it gave notice of its challenge to the licensed patents. *See Studiengesellschaft Kohle, m.b.H. v. Shell Oil Co.*, 112 F.3d 1561 (Fed. Cir. 1997). As such, the ruling that Amgen seeks—that the original Axel patents are unenforceable—would not affect the rights between the parties.

Indeed, this Court has denied a motion to amend when a motion to dismiss has been fully briefed, argued, and taken under advisement. *Cobb v. Supreme Judicial Court of Mass.*, 334 F. Supp. 2d 60, 62 (D. Mass. 2004) (noting that motion to amend was "an obvious effort . . . to avert the dismissal of the case that the court stated was likely to be forthcoming").

B. The Court Should Recommend Remand To The Central District Of California

Regardless of the scope of the Order granting Columbia's motion to dismiss, the Court should address Columbia's pending request for suggestion of remand before considering Amgen's motion to amend. If the Court agrees that the only claims remaining between Amgen and Columbia are Columbia's contract counterclaims pertaining to royalties due on the original Axel patents, then the case should be remanded to the Central District. Similarly, if the Court accepts Amgen's new argument—that Amgen's First and Seventh Claims pertain to royalties due on the original Axel patents—and therefore orders that those claims have *not* been dismissed, then those claims (and Columbia's counterclaims) likewise should be remanded to the Central District of California. In either event, the sole remaining claims would bear no relationship to the premise on which MDL transfer was originally ordered in this case.

The sole basis for MDL consolidation was that every one of the various lawsuits presented common questions regarding *the validity and enforceability of the '275 patent*, not the licensing agreements or the original Axel patents:

All actions can . . . be expected to *share factual and legal questions with respect to the '275 patent* concerning patent validity and related questions such as double patenting, prosecution laches, and inequitable conduct. Centralization under Section 1407 is necessary in order to eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim construction; and conserve the resources of the parties, their counsel and the judiciary.

See JPML Transfer Order (Apr. 21, 2004), at 2 (emphasis added).

This case has been radically transformed in recent months, particularly in the wake of the Court's order granting Columbia's motion to dismiss. The Baxter and Serono lawsuits have settled. Abbott agrees that there is no longer any justiciable controversy between it and Columbia. Johnson & Johnson similarly agrees that none of its claims survived the Court's dismissal order. Wyeth's and Genetic Institute's remaining issues pertain to specific royalty overpayments that those parties allegedly made. Biogen maintains that one of its claims, pertaining to damages that Biogen allegedly suffered when Columbia supposedly wrongfully terminated Biogen's license agreement, survives the Court's dismissal order, but even Biogen admits that this is a unique claim that is unlike any other plaintiff's claim. *See* Joint Report, at p.8. *None* of these other MDL cases involves claims by Columbia that additional royalties are owed under the *original* Axel patents.

In short, whether or not Amgen's First and Seventh Claims for Relief remain, and whether those claims pertain to the original Axel patents, the '275 patent, or both, the MDL backbone that united all of these various cases has disappeared. The claims remaining between Amgen and Columbia are entirely unique. No other plaintiff in this multidistrict litigation, besides Amgen, is attempting to argue that the original Axel patents are invalid or enforceable. No other plaintiff suggests that Columbia's alleged "repressive practices"—with respect to the '275 patent or otherwise—somehow excuse a pre-existing royalty obligation under the original Axel patents. And, most importantly, no other plaintiff is defending against royalty claims arising under the original patents on any basis at all, let alone by asserting that Columbia engaged in "repressive practices" in violation of its license agreement. This Court should

therefore make a suggestion of remand to the JPML and let the Central District of California—which has previously ruled on two of Amgen’s pleadings—take up Amgen’s motion to amend.

C. In The Alternative, The Court Should Deny Amgen's Motion For Leave To Amend Because There Is A Standing Order In This Case Prohibiting Such Amendment

If this Court decides that its November 5, 2004 Order did not dismiss Amgen's First and Seventh Claims for Relief, and further decides not to make a suggestion of remand (or decides to rule on the pending motion regardless), then the Court should deny Amgen's motion to amend.

The Central District of California allowed the filing of Amgen’s third pleading in this action—the Second Amended Complaint—but expressly ruled that, having amended twice, Amgen would not be permitted any further amendments. The district court expressly stated in its Order that “*Further leave to amend will not be granted.*” See Jan. 29, 2004 Order, at n.2, attached as Exh. A (emphasis added).

Amgen now seeks the permission of this Court to file a *fourth* complaint, without bringing to this Court’s attention the January 29, 2004 Order of the Central District of California. Indeed, rather than disclosing this ruling to the Court, Amgen argues that pleading amendments are “liberally allowed” and “freely given,” as if it were never instructed by the Central District of California that additional amendments would *not* be allowed, and as if that ruling were no longer binding upon Amgen.

For obvious reasons of judicial economy and deference, courts generally adhere to orders made by predecessor judges in the same litigation. See, e.g., *Kuenz v. Goodyear Tire & Rubber Co.*, 617 F. Supp. 11 (N.D. Ohio 1985) (“While the court has the power to modify or vacate an order previously entered in the same case by any judge to whom it was assigned and is not precluded from such action by ‘law of the case’ principles, exercise of this power must of necessity be used sparingly. When issues have been carefully considered and decisions

rendered, the only reason which should commend reconsideration of that decision is a change in the factual or legal underpinnings upon which the decisions was based.”); *see also, e.g., In re Jackson Nat’l Life Ins. Co. Premium Litig.*, 209 F.R.D. 134 (W.D. Mich. 2002); *Philadelphia Housing Auth. v. Am. Radiator & Std’d Sanitary Corp.*, 323 F. Supp. 381 (E. D. Pa. 1970).

Here, Amgen has simply urged that its motion should be granted because in the typical case leave should be “freely given,” but has not explained why that liberal standard should apply where the district court has expressly precluded further amendments by the moving party.

V. CONCLUSION

For the foregoing reasons, the Court should clarify that its November 5, 2004 Order dismissed Amgen's First and Seventh Claims for Relief, rule that there are no claims left to amend, and suggest remand of this action to the JPML. Even if the Court determines that one or both of Amgen's claims survived the motion to dismiss, the Court should nevertheless defer ruling on the motion to amend and suggest remand, because, regardless of the viability or scope of Amgen’s claims, the common factual and legal issues that justified MDL transfer no longer exist. If one or both of Amgen's claims survive and the Court chooses not to suggest remand, the Court should deny Amgen's motion for leave to amend in light of the Central District’s earlier ruling precluding further amendments by Amgen, and Amgen’s failure to advise this Court of that ruling.

Dated: December 22, 2004

Respectfully submitted,

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